

REMARKS

Applicants hereby request further consideration of the application in view of the amendments above and the comments that follow.

Applicants respectfully request entry of the foregoing amendments, which place the present application in condition for allowance or in better condition for appeal.

Applicants wish to thank the Examiner for the courtesies extended to Applicants' attorney, David D. Beatty, during the telephonic interview on October 5, 2007.

Claims 22-28 have been cancelled without prejudice as directed to a non-elected invention group, and Applicants reserve the right to pursue these claims in a future divisional patent application.

Status of the Claims

Claims 1-5, 7, 9, 11, 12, 14, 15, 17, 18 and 21 stand rejected under Section 103(a) as being unpatentable over U.S. Patent No. 4,215,198 to Gordon (Gordon) in view of U.S. Patent No. 5,094,955 to Calandra et al. (Calandra). Claims 11-13 and 20 stand rejected under Section 103(a) as being unpatentable over Gordon in view of Calandra and further in view of U.S. Patent No. 4,643,197 to Greene et al. (Greene).

The Rejections under Section 103

Independent Claims 1, 14 and 21 stand rejected under Section 103 over Gordon in view of Calandra. The Action contends that it would have been obvious to one of ordinary skill in the art to employ a sensor as taught by Calandra in the Gordon device and, furthermore, that it would have been obvious to position the sensor on the cap (15, 115) of the device of Gordon. Applicants respectfully disagree.

The device of Gordon is constructed in a manner that would make it unsuitable for modification in the manner suggested by the Action and would prevent the ordinarily skilled artisan from contemplating such modification. While Calandra discloses that the sensor thereof may be placed in proximity to or form a part of a cap, the caps (*e.g.*, the stopper 3 in **Figure 5** and the stopper 4 in **Figure 6**) as illustrated appear to be secure stoppers constructed

to maintain a reliable, gas-tight seal with the container. By contrast, Gordon discloses a hinged cap 15 (or 115) that, as illustrated and described, does not appear capable of providing a robust hermetic seal with the container 11. In particular, the seal between the cap 15 and the container 11 does not appear to be sufficient to adequately withstand the forces associated with the processes as described in Calandra. For example, it does not appear that the seal between the cap 15 and the container 11 would provide an adequate seal when subjected to the stresses attendant to agitation of the specimen, which may be required for optimal growth of microorganisms present in the specimen. The gaseous byproducts generated by a specimen typically generate pressure in the chamber, presenting a risk that such gaseous byproducts would leak or escape from the container 11 of Gordon through the interface with the cap 15 about the inlet port 13, and may even dislodge the cap 15 from the container 11. Such leakage may present several problems. The escaped gas may contaminate the surrounding environment. In particular, the escaped gas may include aerosols containing microorganisms that deposit on an adjacent operator, incubator or the like. Also, the loss of the generated gaseous byproducts may diminish the accuracy, consistency and/or speed of detection by removing the detectable substance (*e.g.*, CO₂) from the container 11. Breach of the seal about the cap 15 may also risk contamination of the sample in the container 11. Therefore, the ordinarily skilled artisan would not consider incorporating the sensor systems of Calandra into the device of Gordon as suggested by the Action.

In view of the foregoing, Applicants respectfully submit that the inventions of Claims 1, 14 and 21 are patentable over the cited art. Claims 2-5, 7, 9, 11-13, 15, 17, 18, 20 and 29-39 each depend from one of Claims 1, 14 and 21 and are therefore allowable over the cited art for at least these reasons. At least certain of the dependent claims are further patentably distinguishable from the cited art.

New Claims 29, 38 and 39 depend from Claims 1, 14 and 21, respectively, and each further recite:

wherein said device has an operative testing orientation and, when said device is in the operative testing orientation, said sensor resides at a lower end of said chamber and below said filter.

For example, as illustrated in **Figures 6 and 7** of Applicants' specification, the device **100** has an operative testing orientation wherein the sensor **120** is located below the filter **130**. Such positioning may ensure that the culturing medium adequately contacts the sensor **120**, which may be a sensor of the type that requires fluid contact to properly react to and indicate the presence of microorganisms or their growth byproducts. Such placement may be particularly valuable when the device is agitated to promote microorganism growth as discussed above. The device of Gordon does not have an operative testing orientation wherein the cap **15** resides at a lower end of the container **11** and below the filter **23**. In view of the leakage risks discussed above, the ordinarily skilled artisan would have regarded inversion of the container **11** of Gordon to be impractical and unsafe.

New Claim 30 depends from Claim 29 and further recites:

30. The device of Claim 29 wherein said end wall is a fixed end wall of said container having a continuous closed surface.

New Claim 31 depends from Claim 30 and further recites:

31. The device of Claim 30 wherein said container is unitary and said inlet and said outlet are the only openings into said container communicating with said chamber.

New Claim 32 depends from Claim 31 and further recites:

32. The device of Claim 31 wherein, when said device is in the operative testing orientation, said inlet and said outlet are each located above said sensor.

Support for Claims 30-32 can be found in Applicants' specification at **Figures 1 and 2**, for example. An integrated filtration and detection device as recited in Claims 30-32 may provide certain distinct advantages. The claimed construction may provide a chamber for the specimen and culturing medium that is hermetically sealed, the hermetic seal being sufficiently robust to withstand agitation (*e.g.*, shaking of the container) and high internal

pressure (e.g., from heating and/or microbial gas production) without breaching the hermetic seal. The claimed construction may permit the container of the device to be inverted to ensure effective and reliable liquid contact between the sensor and the culturing medium without jeopardizing the hermetic seal. The enablement of liquid contact between the culturing medium and the sensor and the ability to safely and reliably withstand agitation and heating may provide for particularly rapid and effective detection of microbial growth in a specimen. As such, integrated filtration and detection devices as recited in Claims 30-32 may be particularly well-suited for on-line or real-time sampling and testing for microbial growth. By contrast, the removable and replaceable cap **15** of Gordon is clearly not a fixed end wall of the container **11**. Accordingly, Claims 30-32 are patentably distinguishable from the cited art for these additional reasons.

New Claims 33 and 34 depend from Claim 1 and are also further patentably distinguishable from the cited art for the reasons discussed above with regard to Claims 30 and 31.

New Claim 35 depends from Claim 1 and further recites:

35. The device of Claim 1 wherein said container includes:
a container body having an end opening opposite said end wall on which said sensor is mounted; and
an end cap secured over and sealing said end opening,
wherein said inlet and said outlet are formed in said end cap.

Applicants respectfully submit that the inventions of Claim 35 as well as Claim 13 would not have been obvious in view of Gordon, Calandra and Greene as applied by the Action to Claim 13. It is not apparent how one of ordinary skill in the art might incorporate both the inlet and the outlet into either the cap **15** or the ball **27** of Gordon. Presumably, any such modification would fundamentally alter the operation and functionality of the Gordon device.

New Claim 36 depends from Claim 1 and further recites:

36. The device of Claim 1 including a liquid culturing medium disposed in said chamber, wherein:

said sensor resides at a lower end of said chamber and below said filter; and
said liquid culturing medium is disposed in said lower end of said chamber and contacts said sensor in said lower end of said chamber.

Claim 36 thus recites the further component of a liquid culturing medium as well as the structural relationships between the chamber, the end wall, the sensor, the filter and the liquid culturing medium. For at least the reasons discussed above with regard to Claim 29, it would not have been obvious to modify the device of Gordon such that the cap **15**, the proposed sensor and the liquid culturing medium are located in or at a lower end of the chamber below the filter **23**.

New Claim 37 depends from Claim 36 and further recites:

37. The device of Claim 36 wherein:
said end wall is a fixed end wall of said container having a continuous closed surface; and
said inlet and said outlet are each located above said sensor.

Claim 37 thus more particularly sets forth the structure of the container and its end wall as well as the structural relationships between the sensor and the inlet and outlet. Accordingly, Claim 37 is also patentably distinguishable from the cited art for the reasons discussed above with regard to Claims 30 and 32.

In re: DiGuseppi et al.
Serial No.: 10/084,578
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Page 12 of 12

CONCLUSION

Applicants respectfully submit that this application is now in condition for allowance, which action is requested. Should the Examiner have any matters outstanding of resolution, he is encouraged to telephone the undersigned at 919-854-1400 for expeditious handling.

Respectfully submitted,




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Katie Wu
Date of Signature: October 8, 2007